

NIH POLICY MANUAL

1793 - LEGISLATIVE PROPOSALS

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1. **Explanation of Material Transmitted:** This a revised manual issuance outlining the policy and procedures by which NIH prepares legislative proposals.

2. **Filing Instructions:**

Remove: NIH Manual 1793, 01/30/91

Insert: NIH Manual Chapter 1793, 09/01/98

3. **Distribution:** NIH Manual Mailing Keys F-401 & F-402

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A. Purpose:

This chapter describes the policy and procedures by which NIH prepares legislative proposals. These proposals are considered by HHS in recommendations to the Office of Management and Budget (OMB) for introduction to the Congress. This chapter is intended to discuss the procedures in general. For each fiscal year's submission, there may be specific HHS requirements which supplement these general instructions, particularly in establishing submission dates from the HHS agencies. Briefly, the purpose of submitting legislative proposals is to: (1) reauthorize programs for which a formal authorization for appropriations is due to expire, (2) correct statutory language that is incorrect or obsolete, or (3) to propose new or revised statutory language which

improves NIH operations or creates new programs. In general, the Department does not seek legislation if regulations or administrative actions can achieve the desired result.

This chapter does not address reports to Congress, or appropriations legislation.

(Refer to NIH Manual 1161, which is pending release.)

B. Background and References:

OMB Circular A-19 includes instructions on the timing and preparation of agency legislative proposals. Generally, sometime early in September, each department must submit its package of legislative proposals to OMB in accordance with OMB Circular A-19. To meet this target date, NIH OLPA sends a request in January to the NIH ICs and OD offices asking them to submit their legislative concepts to OLPA by February. All concepts are reviewed and commented upon by the NIH Legislative Proposal Work Group. NIH ICs and OD offices then submit draft legislative proposals based on review of legislative concepts by the NIH Legislative Proposal Work Group.

Subsequently, all legislative proposals are reviewed and commented upon by the NIH ICs and the OD offices. In addition, all final proposals must be reviewed and approved by the Office of the NIH Legal Advisor and the NIH Director prior to submission to the Department. The Assistant Secretary for Planning and Evaluation (ASPE) asks that OPDIVs submit their legislative proposals by June to accomplish Secretarial initiatives, meet budget targets, improve program management, and reauthorize programs. From June to September, ASPE manages a review process that starts with meetings of the Office of the Secretary Legislative Team and ends with the Secretary's approval of the Department's legislative proposals.

Under the routine budget and legislative review process, OMB reviews the Department's legislative proposals and gives decisions on budget-related, and sometimes non-budget-related, proposals in late November or December ("passback"). Departments may accept or appeal OMB decisions. OMB incorporates approved budget-related proposals into the President's budget and submits them to Congress in January. Once the legislative proposals has been approved, the Department may submit formal bills to the Congress, provide only brief proposal descriptions, or communicate informally with Congress. The Office of the Secretary, Office of the General Counsel, Legislation Division (OS/GC/L), drafts formal bills. In all cases, staff of the Assistant Secretary for Legislation (ASL) work to achieve congressional enactment. No draft legislative proposal should be released to anyone outside the Department until authorized by the Office of the Secretary.

C. Responsibilities:

1. Office of Legislative Policy and Analysis (OLPA): OLPA is responsible for managing the NIH legislative concept and proposal process that involves the development of the NIH legislative proposals formally submitted each year by the Director, NIH, to the Department. OLPA, in collaboration with the NIH

Legislative Proposal Work Group, identifies and consults with IC and OD offices on needed legislative changes; advises on preparing legislative concepts and proposals; reviews recommended legislative concepts and proposals for viability and for meeting NIH program objectives, edits proposals; and checks for consistency with the Department's required format. OLPA is the point of contact between NIH and the Department on legislative proposal matters. Annually, OLPA identifies NIH statutory dollar authorizations or sunset provisions that expire during the target fiscal year. OLPA also assists the ICs and OD offices in determining which legislative proposals from previous years should be resubmitted to the Department.

2. Legislative Proposal Work Group

a. Purpose: In addition to advising the NIH Director on the legislative proposal process and NIH's legislative needs, the Associate Director for Legislative Policy and Analysis, or designee, chairs the Legislative Proposal Work Group, that reviews and comments on legislative concepts and proposals submitted by the NIH ICs and OD offices. The group is the first point of review for submitted legislative concepts. The group will meet on or about the first business day of February to discuss the legislative concepts submitted by the ICs and OD offices. The group may consult with NIH ICs and OD offices regarding submitted legislative concepts and may meet with individual sponsors of concepts to seek further clarification of or provide comment on concepts. NIH ICs and OD offices then submit draft legislative proposals to the NIH Legislative Proposal Work Group.

The Work Group also reviews comments on the legislative proposals provided by the NIH ICs and OD offices. After receiving comments on the proposals from ICs and OD offices, the group shall meet to discuss the comments received. Additional meetings of the group may be held, if necessary, including meetings with individual sponsors of legislative proposals. The comments received, together with any additional recommendations from the group, are provided to the Associate Director for Legislative Policy and Analysis, who, in turn, provides the comments/ recommendations to the individual sponsors of legislative proposals.

Membership. Permanent-- OLPA, OGC, OFM, OMA; Rotating (Term = 1 year) representatives from 3 ICs, appointed by OLPA.

3. Office of the General Counsel (OGC): The Office of the NIH Legal Advisor (hereafter referred to as OGC) reviews the legislative concepts and the proposals developed by NIH for submission to the Department, to identify legal issues related to each concept or proposal and ensure that legal authority is correctly cited. OGC considers whether the proposed legislation is necessary to

accomplish the stated purpose, whether the proposal conforms to authorizing legislation and other relevant statutes, and whether alternative administrative actions are available. OGC also may identify appropriate matters for legislative proposals.

4. Office of Financial Management (OFM): OFM is responsible for determining that legislative concepts and proposals are consistent with the developed or developing budget, including providing budget figures for the budget-related proposals. OFM works with OLPA to integrate NIH's budget with the NIH legislative proposals. Figures for costs, dollar savings and personnel should be consistent with NIH's budget submission for the target fiscal year.

5. Office of Management Assessment (OMA): OMA reviews the legislative concepts and proposals to determine whether alternative administrative remedies are available either through revision of existing regulations or changes in delegation of authorities.

6. ICs and OD offices: The ICs and OD offices, as requested by OLPA, annually prepare legislative concepts and proposals and participate in reviewing and commenting on draft legislative proposals. Prior to submitting legislative concepts or proposals to OLPA, the ICs and OD offices may contact OGC to determine whether legislation is needed to accomplish the desired result. The ICs and OD offices should identify any expiring statutory authorities, including dollar authorizations and sunsets, errors in law and obsolete provisions (e.g., references to organizations under former titles), improvements in economy or efficiency (e.g., eliminating unnecessary reports or committees), desired modifications of or exemptions from statutes, and desirable new programs that would require statutory authority.

D. Procedures:

1. Legislative Concept: ICs and OD offices may have initial discussions of legislative concepts with OGC. The OGC considers whether the proposed legislative concept is necessary to accomplish the stated purpose, whether the proposal conforms to authorizing legislation and other relevant statutes, and whether alternative administrative actions are available. ICs and OD offices submit the legislative concept to OLPA, Shannon Building, Room 244, in February. The legislative concept submitted to OLPA should be no more than one page in length, have a control number at the top of the page, such as NCI-99/01, and should briefly address the following areas: (1) requested change in current law, (2) brief rationale for change, (3) cost/FTE needs, and (4) NIH contact person. No additional supporting documentation should be submitted at this time. The Legislative Proposal Work Group reviews the legislative concepts submitted, reviews any discussion and analysis OGC initially provided to the ICs and OD offices, meets with individual concept sponsors as needed, and makes recommendations to the Associate Director for Legislative

Policy and Analysis regarding the merits of the concept, issues raised during the review, and whether additional supporting documentation is necessary. OLPA provides these recommendations to the individual sponsors of concepts to assist the sponsors in determining whether the concept should be submitted as a full legislative proposal.

2. Legislative Proposal: Legislative proposals are submitted to OLPA in March for subsequent review by OFM, OGC, OMA, and the ICs and OD offices. The Legislative Proposal Work Group meets in March to review comments received during the review process and make recommendations to the Associate Director for Legislative Policy and Analysis regarding the proposals. OLPA provides comments/ recommendations received to the individual sponsors of legislative proposals. After any necessary revisions are made to the proposals, OLPA submits the NIH legislative proposal package to the Director, NIH, in April, for final clearance. In June, the final NIH proposal package is submitted to the Department. See Appendix 1, "Time Line" for the legislative proposal process.

A well-written legislative proposal, or A-19, (see page 2) as it is often called, expedites the review process, enabling people to make decisions with a clear understanding of the issues. A written legislative proposal serves two additional important purposes:

1. It provides an opportunity to explain clearly and succinctly to other departmental officials, the Secretary, the OMB, and congressional staff the sections of the law that need to be changed and why.
2. It guides the HHS Office of the General Counsel in bill drafting. For complex proposals, however, the drafting attorney may need supplemental specifications.

Proposals should adhere to the format that appears in Appendix 2. Legislative proposals should be limited to one or two pages, if possible. A control number as specified in the sample format in Appendix 2 , such as: NCI-99/01, should be included at the top of each proposal. More extensive supporting documentation can be submitted as an attachment, if necessary. The DHHS Legislative Proposal Style Guide outlines specific instructions for preparing each section of the legislative proposal, as well as sample legislative proposals for reference. The "Style Guide" is updated annually, and may be obtained from OLPA.

E. Records and Retention and Disposal:

For this chapter, records pertaining to Legislative Proposals are retained and disposed of under the authority of NIH Manual [1743](#), "Keeping and Destroying Records," Item 1100-A-2, which states:

1100-A-2 Legislative proposals which have not yet been enacted into law. Included are

supporting documents such as testimony before congressional committees and studies assessing existing authorities to meet present and future program objectives.

Disposition: Review for disposal at least every 5 years and destroy what is not needed for administrative reference. Earlier disposal is authorized.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to members of Congress or Congressional committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are sometimes retained for significant periods of time, e-mail messages and attachments may be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

F. Management Controls:

The purpose of this manual issuance is to establish the policy and procedures by which NIH prepares legislative proposals.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter (Issuing Office): OLPA
2. Frequency of Review (in years): Annual
3. Method of Review:

Other Review (describe): Annual Compliance Assessment conducted by Legislative Proposal Work Group. This assessment will ensure targeted offices are complying with this policy and the requirements associated with legislative concepts and legislative proposals. A report will be developed for the Director, OLPA that describes how the policies and procedures were tested and any problems and/or issues identified for correction.

4. Review Report to be sent to: Deputy Director for Management

Appendices:

Appendix 1. Time Line

- January OLPA requests legislative concepts from ICs and OD offices. In consultation with OGC, the ICs, and OD offices, OLPA identifies NIH statutory dollar authorizations or sunset provisions that expire during the target fiscal year. OLPA assists the ICs and OD offices in determining which legislative proposals from previous years should be resubmitted to the Department.
- February ICs and OD offices submit legislative concepts to OLPA. OLPA convenes Legislative Proposal Work Group to review legislative concepts submitted. Subsequent meetings of the Work Group may be held with individual sponsors of legislative concepts as deemed necessary by the Work Group.
- March OLPA requests ICs and OD offices to submit draft legislative proposals to OLPA, based upon comments of the Legislative Proposal Work Group. OLPA submits draft legislative proposals for review and comment to OFM, OGC, OMA, the ICs, and OD offices. When comments are received, OLPA convenes Legislative Proposal Work Group to discuss comments received and make recommendations to the Associate Director for Legislative Policy and Analysis.
- April OLPA provides comments/recommendations received to the individual sponsors of legislative proposals. After any necessary revisions are made to the proposals, OLPA submits the package of NIH legislative proposals to the Director, NIH, for final clearance.
- May OLPA prepares final legislative proposal package based on comments received from the Director, NIH.
- June OLPA submits final NIH legislative proposal package to the Department. OLPA meets with appropriate NIH ICs and OD offices that have submitted legislative proposals in order to prepare for presentations before the HHS OS Legislative Team. OLPA meets with the HHS OS Legislative Team to discuss the NIH legislative proposals.
- September Department submits NIH legislative proposal package as a part of the HHS legislative proposal package to OMB for clearance.
- November OMB informs the Department of its determinations regarding the Department's legislative proposal package.
- December Department puts package of legislative proposals in final and begins drafting legislative language, if necessary.

Appendix 2. Legislative Proposal Format:

Control Number

(e.g., NCI 99/01)

Title of Six Words or Less

State in Program, Not Legal, Terms What You Seek to Accomplish. Keep It Four Lines or Less.

Current Law: Describe fully (not merely cite), without jargon, all portions of law that proposal would amend and that make the proposal necessary.

Proposal: State proposal in detail, beginning with any VERB except "amend"; describe proposal; Do not advance specific technical legal language; General Counsel attorneys will do this.

Rationale: Include the following, as applicable:

A. Describe problems proposal would solve and how it would solve them. Cite supporting research or reports, if any. Do not introduce new elements/proposals here.

B. Explain whom proposal would significantly affect, extent of this effect, and approximate number of individuals affected. Explain effects on beneficiaries.

C. Describe whether and how proposal would affect the roles, rights, or responsibilities of states or would result in an unfunded mandate being imposed upon the states, local governments, tribal governments, or private sector. Indicate whether and by how much the proposal would increase or reduce costs or burdens on states and local governments. Describe any effects on service providers or other institutions.

Cost: Label this section "Cost," "Revenue," or "Authorization Level," as appropriate. Provide a table showing estimated costs, savings, revenues, or reauthorization level, in millions of dollars. Give estimates for five years. For reauthorization requests, first year must contain the same number reflected in your budget submission; use "Such Sums As Necessary" for outyears. If no costs, savings, or revenues, say "None." Explain how you calculated estimates.

Personnel Requirements: Show estimated personnel impact in full-time equivalents (FTEs). Give estimates for the same fiscal years for which you gave cost estimates. If no personnel impact, OMIT section.

Effective Date: Omit UNLESS the proposal is effective on a date other than the beginning of the first day of the fiscal year indicated in the "Cost" section.

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